UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL W. JOHNSON

Appeal 2007-2766
Application 09/880,615
Technology Center 3700

Decided: October 17, 2007

Before DEMETRA J. MILLS, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the Examiner's final rejection of claims 23, 24, 26-30, 32, 33, and 35-40. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are directed to methods of manufacturing a porous stent. The stent is described as useful to deliver drugs to a desired body location by loading stent pores with drug (Specification 1: 28-29; 3: 4-20).

Claims 23, 24, 26-33, and 35-41 are pending (Supp. Appeal Br. 3). Claims 31 and 41 are withdrawn; claims 23, 24, 26-30, 32, 33, and 35-40 stand rejected (Supp. Appeal Br. 3). Two grounds of rejection are appealed:

1) Claims 23, 26-30, 32, 35-37, and 39 stand rejected under 35 U.S.C. § 103(a) as obvious over Yan (U.S. Pat. No. 5,843,172, Dec. 1, 1998) in view of Solovay (U.S. Pat. No. 5,769,884, Jun. 23, 1998) (Answer 3); and

2) Claims 24, 33, 38, and 40 stand rejected under 35 U.S.C. § 103(a) as obvious over Yan in view of Solovay, further in view of Richter (U.S. Pat. No. 5,807,404, Sep. 15, 1998) (Answer 5).

We select claims 23, 24, and 32 as representative of the appealed claims. Claims 23, 24, and 32 read as follows:

> 23. A method of manufacturing a stent comprising the steps of:
> providing a tube, the tube characterized by a longitudinal axis, having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, and
> subsequently cutting a stent from the tube.
>
> 24. The method of claim 23 wherein a first portion of the tube is made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube is made from a second metal different from the first metal.
>
> 32. A method of manufacturing a stent comprising the steps of:
> providing a tube having at least two different longitudinally spaced regions of different predetermined porosities; and
> subsequently, cutting a plurality of openings in the tube to form a stent having multiple serpentine bands such that a first band has a different porosity than a second band.

The manufacturing process recited in independent claims 23 and 32 involve two steps: 1) providing a tube; and 2) cutting a stent from the tube. In claim 32, the stent is cut into a serpentine pattern. The tube in both claims 23 and 32 is characterized by having at least two different pores sizes along the longitudinal axis.

FINDINGS OF FACT

The level of skill in the art

1. Stents are commonly used to treat medical conditions (*see* Solovay, at col. 1, ll. 9-12; Yan, at col. 1, ll. 12-20; Richter, at col. 1, ll. 16-23).

2. The manufacture of stents using different designs and different materials was known and routine in the art prior to the application filing date (*see* Yan, at col. 4, ll. 32-40; at col. 9, ll. 15-40; Solovay, at col. 7, ll. 4-23; Richter, at col. 1, ll. 43-48).

3. Different methods of manufacturing stents were also known and routine to persons of ordinary skill in the art (*see* Yan, at col. 2, ll. 38-46; at col. 7, ll. 45-50; Solovay, at col. 7, ll. 45-47; Richter, at col. 1, ll. 50-54).

The scope and contents of the prior art

The Yan Patent

4. Yan describes a stent having porous cavities which "can be formed by sintering the stent material from metallic particles, filaments, fibers or other materials" (Yan, at col. 2, ll. 7-9).

5. Drugs can be loaded into the pores (Yan, at col. 1, ll. 64-66).

6. "The stent can be formed from a sintered cylindrical tube or sintered metal sheet which can be laser cut or chemical etched into an expandable stent structure" (Yan, at col. 2, ll. 11-14; at col. 2, ll. 39-46; Answer 4).
7. "A sheet or tube of sintered metal can be cut in the desired shape to form the metal structural member with a laser, such as a continuous CO_2 laser, a pulsed YAG laser, or an excimer laser, for example, or alternatively, by chemical etching or stamping" (Yan, at col. 7, ll. 44-49).
8. The stent described by Yan can comprise outer and inner core layers comprising pores of different diameters, where the core's pores have a larger diameter than the pores of the outer layer to control the rate at which drugs are released into the walls of the vessel (Yan, at col. 2, ll. 20-32; at col. 8, ll. 52-55; *see* Fig. 12. *See* also Answer 3).

The Solovay Patent

9. Solovay describes a stent covering which has different porosities along its length (Answer 5). Typically, tissue ingrowth and re-endothelialization are desired at the ends of the stent. To encourage ingrowth into this region, the stent covering "is more porous, and in those regions w[h]ere it is desirable to inhibit such ingrowth, the stent covering is substantially non-porous" (Solovay, Abstract; *see* also at col. 2, ll. 2-9; at col. 3, ll. 35-41; Fig. 6).
10. Ingrowth can also be controlled by pore size and density, using smaller diameter and/or less dense porosity to inhibit ingrowth, and larger diameter and higher porosity to encourage it (Solovay, at col. 2, ll. 2-41; at col. 4, ll. 53-67; Fig. 6).
11. Each longitudinally spaced region of different porosity has the same porosity around its circumference (*see* Solovay, Fig. 6; Answer 5).

12. The stent covering can be disposed on a suitable expandable frame (Solovay, at col. 7, ll. 25-44).

13. A "nonuniform porosity stent" can be prepared from any suitable material; such as a polymer that consists of an extruded tube (Solovay, at col. 7, ll. 4-14).

14. The stent's pores "may be filled with a material, such as drug or protein" (Solovay, at col. 6, ll. 47-55; Answer 5).

15. Solvay describes a preferred embodiment in which a braided porous stent covering is produced on a mandrel and then cut to its desired length (Solovay, at col. 8, ll. 19-30; *see* Fig. 7).

The Richter Patent

16. Richter teaches a stent comprised of C-shaped, U-shaped, and S-shaped loops (Richter, at col. 3; at col. 6, ll. 42-60; Fig. 11; Answer 6).

17. The flexibility of the loops can vary from loop to loop. The different flexibilities may be accomplished by using different materials in the different loops, such as different metals (Richter, at col. 6, ll. 42-51; at col. 10, ll. 38-40; Answer 6).

REJECTION OVER YAN IN VIEW SOLOVAY

Claims 23, 26-30, 32, 35-37, and 39 stand rejected under 35 U.S.C. § 103(a) as obvious over Yan in view of Solovay.

Claims 23 and 32 are directed to a manufacturing process comprising: 1) providing a tube characterized by having at least two different pores sizes along its longitudinal axis; and 2) cutting a stent from the tube. Claim 32 is directed to a manufacturing process involving a tube of the same non-uniform porosity characteristics recited in claim 23, but it further limits the

cutting step to "cutting a plurality of openings in the tube to form a stent having multiple serpentine bands such that a first band has a different porosity than a second band."

In making an obviousness determination over a combination of prior art references, it is important to identify a reason why persons of ordinary skill in the art would have attempted to make the claimed subject matter. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). When making such a determination, the scope of the prior art and level of ordinary skill must be considered. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

Both Yan (FF 6-7) and Solovay describes the same basic manufacturing steps (FF 15) which are claimed, i.e., of providing a tube and cutting it. The issue in this rejection is whether the skilled worker would have had sufficient reason to have supplied the patterned stent of Yan "with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, . . . in light of the teachings of Solovay" (Answer 5). If so, the burden shifts to Appellant to come forward with rebuttal arguments or evidence. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *Hyatt v. Dudas*, 492 F.3d 1365, 1370, 83 USPQ2d 1373, 1375-76 (Fed. Cir. 2007).

In the instant Specification, it is stated that "cellular ingrowth [into the porous stents of the present invention] is sometimes desirable" (Specification 4: 5). The Specification also states that pore size determines whether cellular infiltration will occur and states that "pore size of the stent may be varied to foster or inhibit cellular infiltration and/or tissue ingrowth"

(Specification 4: 6-14). Solovay's stent covering is designed around these same principles (FF 9-10); thus, the Specification's statements about cell ingrowth and infiltration had been known in the prior art.

Solovay places smaller diameter pores in middle regions to inhibit ingrowth and larger diameter pores in end regions to encourage cell ingrowth (FF 9-10). Thus, skilled workers at the time of the invention would have known, based on Solovay's teachings, that changing stent porosity allows the ingrowth to be manipulated. Appellant admits in the Specification that cellular ingrowth into a stent may be desirable (*see supra*; Specification 4: 6-14). Therefore, the skilled worker would have had reason at the time the invention was made to apply Solovay's teaching about non-uniform porosity in a covered stent to other stent designs – such as the claimed stent – for the advantages described by Solovay. Persons of skill in the art being familiar with stent use, design, and manufacture would have considered the application of Solovay's teaching about covered stents to the particular class of stents described in Yan as a routine exercise of their skills (FF 1-3), including stents with serpentine patterns as recited in claim 32.

Appellant contends that Solovay discloses a stent cover which is "placed about a stent" (Appeal Br. 7). He asserts that a "skilled person in the art will not look to the stent cover art to find a method for manufacturing a stent having longitudinally spaced regions of different predetermined porosities" (Appeal Br. 7).

We do not find this argument persuasive. As stated above, Appellant admits in the Specification (Specification 4: 5) that it may be desired to have ingrowth into the stent – the same event that is described by Solovay as desirable for its stent covering (FF 9). Appellant even explains that this

would be accomplished by varying the pore size of the stent material – the same solution taught by Solovay (FF 10). In other words, Solovay's teaching about stent coverings is applicable to non-covered stents – which is logical because the exterior of the stent covering would be exposed to the body cavity as would be the exterior of the non-covered stent.

Solovay also teaches that it may be desirable to discourage growth in certain regions of the stent covering, and suggests non-uniform porosity to address this problem (FF 9-10). It is reasonable that such benefit would also extend to non-covered stents, such as the stent described by Yan, because its exterior is also exposed to the body cavity. Accordingly, the skilled worker would have had reason to apply the teachings of Solovay to Yan's non-covered stent.

Appellant also argues "if one were to take the stent cover of Solovay and then cuts [sic] it as one would in forming a stent, the very purpose of the Solovay stent cover would be destroyed; the stent cover would at best now sparsely and intermittently cover the stent and the struts of the stents and would likely interfere with stent expansion as the serpentine portions of the cut stent cover would become tangled with the serpentine bands of the stent." (Appeal Br. 8). As explained above, the rejection does not require cutting Solovay's stent into a serpentine pattern, but rather applying Solovay's teaching to patterned non-covered stents, such as Yan's stent.

Appellant urges that

> column 4 lines 58-64 of Yan which teaches uniform porosity and the undesirability of areas of different porosity. As the explicit language of the Yan reference teaches the undesirability of areas of different porosity, it does not make sense that Yan would teach longitudinally spaced regions of different predetermined physical porosities. In fact, Yan teaches

> away from such a teaching; one would never predetermine to produce the very thing that is undesirable (i.e. non-uniform porosity).

(Appeal Br. 6.)

We do not agree. Yan states that consistent pore size and consistent distribution of pores ensures even distribution of drug within the stent and even distribution of drug in contact with the stent (Yan, at col. 4, ll. 54-65). Thus, the teaching of Yan cited by Appellants deals with the issue of drug delivery, and not the separate problem of tissue ingrowth addressed by Solovay. However, claims 23 and 32 do not recite that drug is present in the stent; thus, even were this consideration relevant, it would only be relevant to the extent that the stent in the claimed method loaded with drug.

Nevertheless, we are not convinced by Appellant's argument because Solovay also teaches that that its stent of non-uniform porosity may be loaded with drug (FF 14). Thus, we do not find that persons of skilled in the art would have been discouraged from applying Solovay's teaching to Yan's stent since Solovay also teaches loading the stent pores with drug.

Appellant contends that the Examiner erred because of his repeated assertions that "that Yan discloses providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics" which is *inconsistent* with Yan's teaching that the stent must have uniform porosity (Appeal Br. 5-6).

The Examiner's characterization of Yan is correct. Yan shows an embodiment of a stent in Fig. 12 having a core layer of large diameter pores surrounded by a top and bottom layers of smaller diameter pores (FF 8). Thus, there are different porosities at different regions along the length of

the stent, where each of the different porosities extends along the entire length of the stent.

In sum, we conclude that there is sufficient evidence to establish prima facie obviousness of claims 23 and 32. Claims 26-30, 35-37, and 39 fall with claims 23 and 32 because separate arguments for their patentability were not provided. *See* 37 C.F.R. 41.37(c)(1)(vii) (2006).

REJECTION OVER YAN IN VIEW OF SOLOVAY AND RICHTER

Claims 24, 33, 38, and 40 stand rejected under 35 U.S.C. § 103(a) as obvious over Yan in view of Solovay and Richter.

We select claim 24 as representative of the claims for the purpose of deciding this rejection. Claim 24, which depends on claim 23, recites that "a first portion of the tube is made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube is made from a second metal different from the first metal."

The Examiner contends that Richter discloses a stent comprising first and second serpentine segments which are made of first and second metals, respectively (FF 16, 17; Answer 6). The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to have modified Yan's stent with Richter's teaching "in order to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted" (Answer 7). Appellant does not identity any defect in the Examiner's reasoning, and as we find none, we affirm the Examiner's rejection of claim 24. Claims 33, 38, and 40 fall with claim 24 because separate arguments for their patentability were not provided. *See* 37 C.F.R. 41.37(c)(1)(vii) (2006).

CONCLUSION

The Examiner's final rejection of all pending claims is affirmed.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

Ssc:

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